

USSN 10/506,345

Att. Docket No. 1103326-0777

Page 2 of 11

RECEIVED  
CENTRAL FAX CENTER

AUG 28 2006

**Amendments to the Claims**

**The following listing of claims will replace all prior versions and listings of claims in the application.**

1. (Previously presented) An  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole, wherein:

$\text{R}_1$  is a linear or branched  $\text{C}_1\text{-C}_{12}$ -alkyl group, or a cyclic  $\text{C}_3\text{-C}_{12}$ -alkyl group, wherein the linear or branched  $\text{C}_1\text{-C}_{12}$  alkyl group is optionally substituted or interrupted with a substituent selected from the group consisting of a cyclic  $\text{C}_3\text{-C}_6$ -alkyl group, a cyclic  $\text{C}_3\text{-C}_6$ -alkylene group, a phenyl group, and a phenylene group, and wherein the cyclic  $\text{C}_3\text{-C}_6$ -alkyl group, the cyclic  $\text{C}_3\text{-C}_6$ -alkylene group, the phenyl group, or the phenylene group is optionally further substituted by 0, 1, 2, or 3 methyl groups; and

$\text{R}_2$  and  $\text{R}_3$  are hydrogen.

2. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole according to claim 1, wherein  $\text{R}_1$  is a linear or branched  $\text{C}_1\text{-C}_6$ -alkyl group, or a cyclic  $\text{C}_3\text{-C}_6$ -alkyl group, wherein the linear or branched  $\text{C}_1\text{-C}_6$ -alkyl group is optionally substituted or interrupted with a substituent selected from the group consisting of a cyclic  $\text{C}_3\text{-C}_5$ -alkyl group, a cyclic  $\text{C}_3\text{-C}_5$ -alkylene group, a phenyl group, or a phenylene group, and wherein the cyclic  $\text{C}_3\text{-C}_5$ -alkyl group, the cyclic  $\text{C}_3\text{-C}_5$ -alkylene group, the phenyl group, or the phenylene group is optionally further substituted by 0, 1, 2, or 3 methyl groups.

3. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole according to claim 1, wherein  $\text{R}_1$  is a linear, branched, or cyclic  $\text{C}_4$ -alkyl group, wherein the linear or branched  $\text{C}_4$ -alkyl group is optionally substituted or interrupted with a cyclic  $\text{C}_3$ -alkyl group or a cyclic  $\text{C}_3$ -alkylene group, and wherein the cyclic  $\text{C}_3$ -alkyl group or the cyclic  $\text{C}_3$ -alkylene group is further substituted by 0, 1, 2, or 3 methyl groups.

USSN 10/506,345

Atty. Docket No. 1103326-0777

Page 3 of 11

4. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole according to claim 1, wherein the salt has a pKa value equal to or greater than about 10.
5. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole according to claim 1, wherein the salt has a pKa value equal to or greater than about 10.5.
6. (Canceled)
7. (Canceled).
8. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole according to claim 1, wherein the salt is the *tert*-butylammonium salt of omeprazole.
9. (Canceled)
10. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole according to claim 1, wherein the salt is crystalline.
11. (Previously presented) A process for preparation of an  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole according to any one of claims 1-5, 8, or 10, which comprises the steps of:
  - a) dissolving omeprazole in an organic solvent;
  - b) adding an  $\text{NR}_1\text{R}_2\text{R}_3$  compound and precipitating the desired salt; and
  - c) isolating and drying the obtained salt of omeprazole.
12. (Previously presented) The process according to claim 11, wherein the organic solvent is acetonitrile or *tert*-butyl methyl ether.
13. (Canceled)
14. (Canceled)
15. (Previously presented) A pharmaceutical composition comprising the  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole according to any one of claims 1-5, 8, or 10 as active ingredient in association with

pharmaceutically acceptable excipients and optionally one or more additional therapeutic ingredients.

16. (Canceled) ,

17. (Previously presented) A method for inhibiting gastric acid related secretion comprising administering to a patient suffering from the condition a therapeutically effective amount of the  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt according to any one of claims 1-5, 8, or 10.

18. (Previously presented) An  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of esomeprazole, wherein:

$\text{R}_1$  is a linear or branched  $\text{C}_1$ - $\text{C}_{12}$ -alkyl group, or a cyclic  $\text{C}_3$ - $\text{C}_{12}$ -alkyl group, wherein the linear or branched  $\text{C}_1$ - $\text{C}_{12}$  alkyl group is optionally substituted or interrupted with a substituent selected from the group consisting of a cyclic  $\text{C}_3$ - $\text{C}_6$ -alkyl group, a cyclic  $\text{C}_3$ - $\text{C}_6$ -alkylene group, a phenyl group, and a phenylene group, and wherein the cyclic  $\text{C}_3$ - $\text{C}_6$ -alkyl group, the cyclic  $\text{C}_3$ - $\text{C}_6$ -alkylene group, the phenyl group, or the phenylene group is optionally further substituted by 0, 1, 2, or 3 methyl groups; and

$\text{R}_2$  and  $\text{R}_3$  are hydrogen.

19. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of esomeprazole according to claim 18, wherein  $\text{R}_1$  is a linear or branched  $\text{C}_1$ - $\text{C}_6$ -alkyl group or a cyclic  $\text{C}_3$ - $\text{C}_6$ -alkyl group, wherein the linear or branched  $\text{C}_1$ - $\text{C}_6$  alkyl group is optionally substituted or interrupted with a substituent selected from the group consisting of a cyclic  $\text{C}_3$ - $\text{C}_5$ -alkyl group, a cyclic  $\text{C}_3$ - $\text{C}_5$ -alkylene group, a phenyl group, or a phenylene group, and wherein the cyclic  $\text{C}_3$ - $\text{C}_5$ -alkyl group, the cyclic  $\text{C}_3$ - $\text{C}_5$ -alkylene group, the phenyl group, or the phenylene group is optionally further substituted by 0, 1, 2, or 3 methyl groups.

20. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of esomeprazole according to claim 18, wherein  $\text{R}_1$  is a linear, branched, or cyclic  $\text{C}_4$ -alkyl group, wherein the linear or branched  $\text{C}_4$ -alkyl group is optionally substituted or interrupted with a cyclic  $\text{C}_3$ -alkyl group or a cyclic  $\text{C}_3$ -alkylene group, and wherein the cyclic  $\text{C}_3$ -alkyl group or the cyclic  $\text{C}_3$ -alkylene group is further substituted by 0, 1, 2, or 3 methyl groups.

21. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of esomeprazole according to claim 18, wherein the salt has a  $\text{pK}_a$  value equal to or greater than about 10.

22. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of esomeprazole according to claim 18, wherein the salt has a  $\text{pK}_a$  value equal to or greater than about 10.5.

23. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of esomeprazole according to claim 18, wherein the salt is the *tert*-butylammonium salt of esomeprazole.

24. (Previously presented) The  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of esomeprazole according to claim 18, wherein the salt is crystalline.

25. (Previously presented) A process for preparation of an  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of esomeprazole according to any one of claims 18-24, which comprises the steps of:

- a) dissolving esomeprazole in an organic solvent;
- b) adding an  $\text{NR}_1\text{R}_2\text{R}_3$  compound and precipitating the desired salt; and
- c) isolating and drying the obtained salt of esomeprazole.

26. (Previously presented) The process according to claim 25, wherein the organic solvent is acetonitrile or *tert*-butyl methyl ether.

US\$N 10:506,345

Any. Docket No. 1103326-0777

Page 6 of 11

27. (Previously presented) A pharmaceutical composition comprising the  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of csomeprazole according to any one of claims 18-24 as active ingredient in association with pharmaceutically acceptable excipients and optionally one or more additional therapeutic ingredients.

28. (Previously presented) A method for inhibiting gastric acid secretion comprising administering to a patient suffering from the condition a therapeutically effective amount of the  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt according to any one of claims 18-24.

29. (Canceled)